

C/ agents, antimanic agents, antidepressants, antiobesity agents, behavior modifiers, psychostimulants, neurostimulants, abuse deterrents, anxiolytics, antipsychotics, antianaphylactic agents, antihistamines, antipruritics, anti-inflammatory agents, bronchodilators, antiasthmatic agents, cystic fibrosis therapy agents, mast-cell stabilizers, steroids, xanthines, anticholinergic agents, bioactive peptides, polypeptides, hormones, drugs acting at neuroeffector junctional sites, prostaglandins, narcotics, hypnotics, alcohols, psychiatric therapy agents, anti-cancer chemotherapy agents, drugs affecting motility, oral hypoglycemics, androgens, estrogens, nutraceuticals, herbal medications, insulin, serotonin receptor agonist, serotonin receptor antagonists, alternative medicines, amino acids, dietary supplements, analeptic agents, respiratory agents, cold remedies, cough suppressants, antimycotics, bronchodilators, constipation aids, contraceptives, decongestants, expectorants, motion sickness products, and homeopathic preparations.

REMARKS

The Pending Claims

Prior to entry of the above amendments, Claims 96-138 are pending in this application. Claims 96-108, 114-127, and 137-138 are directed to an anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition. Claims 109-111 relate to a method of delaying gastric emptying and promoting absorption; Claims 112-113 relate to a method of enhancing bioavailability of pharmaceutical preparations; Claims 128-130 are directed to a method of delaying gastric emptying and prolonging small intestine transit time while promoting an anti-atherogenic and/or anti-diarrheal effect and/or promoting digestion, dissolution and/or absorption; and Claims 131-136 relate to a method of treating a nutritional deficiency or medical condition.

Applicant's Amendments to the Claims

The amendment to Claim 119, with respect to “Alzheimer’s therapy” is to correct obvious typographical errors.

The Office Action, Applicant’s Request for Reconsideration and Withdrawal of the Restriction Requirement, and Applicant’s Provisional Election

The Examiner required restriction, under 35 U.S.C. § 121, and required Applicant to elect a single invention to which the claims must be restricted. The Examiner also stated that Claims 96 and 114 are generic.

The Examiner designated the following three claim groups:

1. Group I; Claims 96-113, and 137, which the Examiner characterized as being drawn to a composition and method for promoting gastric emptying.
2. Group II; Claims 114-130, and 138, which the Examiner characterized as being drawn to a composition and method for delaying gastric emptying.
3. Group III; Claims 131-136, which relate to a method of treating a nutritional deficiency or medical condition.

Applicant strongly traverses the restriction requirement, but as required by 37 C.F.R. § 1.143, provisionally elects **Group II**. Applicant’s election is made with a complete reservation of all rights under 35 U.S.C. § 121.

Applicant respectfully requests the Examiner to reconsider and withdraw the requirement, because the restriction requirement was based on an arbitrary mischaracterization of the claims of Group I, as being “drawn to a composition and method for *promoting* gastric emptying.” For example, the preambles of Claim 96 (designated claim Group I) and Claim 114 (designated claim Group II) both recite a composition that is inter alia “. . . *absorption promoting* . . . and/or gastric emptying *slowing*,” i.e., delaying gastric emptying. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the requirement, at least with respect to designated Claim Groups I and II, because the restriction requirement was based on an arbitrary mischaracterization of the claims in designated Group I.

Examiner's Requirement of an Election of Species and Applicant's Response

The Examiner required elections of species, under 35 U.S.C. § 121. The Examiner presented the following species of the claimed invention for election:

- (a) capsules;
- (b) coated and uncoated microspheres;
- (c) coated and uncoated particles;
- (d) encapsulated microspheres;
- (e) encapsulated particles;
- (f) coated tablet;
- (g) uncoated tablet;
- (h) aqueous and oily suspensions, emulsion;

(i) dispersible powders or granules;

(j) syrups and elixirs;

(k) troches and lozenges;

Applicant elects: (a) capsules

Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121.

The Examiner stated that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim. The Examiner stated that currently Claims 96 and 114 are generic. Applicant respectfully submits that claims, including Claims 96-100, 106-119, and 125-136 are also generic with respect to the species (a)-(k) designated by the Examiner.

Respectfully submitted,

By: 

Nisan A. Steinberg, Ph.D.
Reg. No. 40,345

SIDLEY AUSTIN BROWN & WOOD LLP
555 West Fifth Street
Los Angeles, California 90013
Ofc: 213-896-6665
Fax: 213-896-6600

VERSION WITH MARKINGS TO SHOW CHANGES MADE**In the Claims**

119. (Amended) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 117, wherein the pharmacological agent is selected from the group consisting of somatostatin analogues, insulin release inhibitors, anti-diarrheal agents, antibiotics, fiber, electrolytes, analgesics, antipyretics, migraine treatment, migraine prophylaxis, antifungal agents, antiviral agents, Quinolones, AIDS therapeutic agents, anti-infectives, aminoglycosides, antispasmodics, parasympathomimetics, anti-tuberculous agents, anti-malarial agents, vaccines, anti-parasitic agents, cephalosporins, macrolides, azalides, tetracyclines, penicillins, anti-arthritis therapy agents, gout therapy agents, nonsteroidal anti-inflammatory agents, gold compounds, antianemic agents, antianginal agents, antiarrhythmics, anticoagulants, post-MI agents, vasodilators, beta-adrenergic blockers, calcium channel blockers, nitrates, thrombolytic agents, anticoagulants, antifibrotic agents, hemorrhologic agents, antiplatelet agents, vitamins, antihemophilic agents, heart failure agents, ACE inhibitors, cardiac glycosides, blood flow modifying agents, bile salts, growth promoting agents, growth suppressive agents, sympathomimetics, inotropic agents, antihypertensive agents, central alpha-adrenergic agonists, peripheral vasodilator, sympatholytics, diuretics, diuretic combinations, mineral supplements, hypolipemic agents, acne treatments, antidiarrheal agents, anti-nauseants, antiemetics, antispasmodics, antiulcer, antireflux agents, appetite suppressants, appetite enhancers, gallstone-dissolving agents, gastrointestinal anti-inflammatory agents, antacids, antiflatulents, anti-gas agents, laxatives, stool softeners, digestants, digestive enzymes, enzyme supplements, [a]Alzheimer's therapy, anticonvulsants, antiparkinson agents, sedatives, benzodiazepines, benzodiazepine receptor antagonists, receptor agonists, receptor antagonists, interferons, immunosuppressive therapy, immunomodulatory agents, muscle relaxants, hypnotics, anti-anxiety agents, antimanic agents, antidepressants, antiobesity agents, behavior modifiers, psychostimulants, neurostimulants, abuse deterrents, anxiolytics, antipsychotics, antianaphylactic agents, antihistamines, antipruritics, anti-inflammatory agents, bronchodilators, antiasthmatic agents, cystic fibrosis therapy agents, mast-cell stabilizers, steroids, xanthines, anticholinergic agents,

bioactive peptides, polypeptides, hormones, drugs acting at neuroeffector junctional sites, prostaglandins, narcotics, hypnotics, alcohols, psychiatric therapy agents, anti-cancer chemotherapy agents, drugs affecting motility, oral hypoglycemics, androgens, estrogens, nutraceuticals, herbal medications, insulin, serotonin receptor agonist, serotonin receptor antagonists, alternative medicines, amino acids, dietary supplements, analeptic agents, respiratory agents, cold remedies, cough suppressants, antimycotics, bronchodilators, constipation aids, contraceptives, decongestants, expectorants, motion sickness products, and homeopathic preparations.